PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Appellants	:	Kramer, et al.	
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APPELLANTS' APPEAL BRIEF

Dear Sir:

This is an Appeal from a final Office Action dated December 6, 2005, rejecting claims 19-27, 32-34, and 37-42. These claims having been at least twice rejected. Appellants, having filed a Notice of Appeal (filed February 22, 2006) within the time period provided under § 1.134 accompanied by the fee set forth in 37 C.F.R. § 41.20(b)(1), do hereby submit this Brief prior to the two-month deadline of April 24, 2006 (because April 22 fell on a Saturday) along with the fee set forth in §41.20(b)(2). If any of this is incorrect, the Commissioner is hereby authorized to charge any additional fee that may be due, or credit any overpayment, to Deposit Account No. 19-2112.

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Note: Neither an Evidence Appendix nor a Related Proccedings Appendix is included because both are inapplicable in this case.

I. REAL PARTY IN INTEREST

The real parties in interest are Valentin Kramer and Bruce Rueffer, the named inventors.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 19-27, 32-34, and 37-42 are pending, and the rejection of each of those claims is being appealed.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final Office Action dated December 6, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The instant Application includes two independent claims, claims 19, 32, and 37.

Claim 19

Claim 19 is drawn to a PTFE article (see FIG. 1). The article is created by forming a mixture of a first resin and a second resin. See e.g., Specification Page 5, lines 20-34. The first resin and second resins have different molecular weights. Id. The article is produced by expanding it. Id. at 30.

The resulting article comprises an internodal arrangement between a first node and a second node. These nodes are labeled for demonstrative purposes in the reproduction of FIG. 2 below:

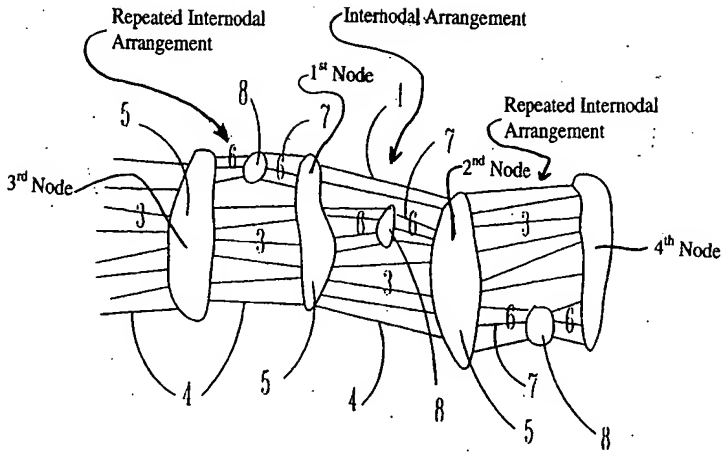

Fig. 2

3 = large pores
4 = fibrils between large solid nodes
5 = elongated nodes
6 = small pores
7 = short fibrils
8 = small/intermediate nodes

Corresponding claim terminology has been added to the above. It did not appear in the originally filed version of FIG. 2, but has been added to show where the claimed features are supported in the embodiment disclosed. The arrangement includes a first plurality of fibrils 4 interconnecting a first node with a said second node. The first plurality of fibrils 4 defines a first group of pores therebetween. These pores fall substantially within a first size range. See Specification Page 2, Line 35 – Page 3, Line 13. The arrangement also includes an intermediate node 8 which is substantially smaller than said first and second nodes. See FIG. 2, reproduced above. A second plurality of fibrils 7 attach the intermediate third node between the first and second nodes. See FIG. 2. This second plurality of fibrils defines there between a second group of smaller pores 6 which fall substantially within a second size range. Specification Page 2, Line 35 – Page 3, Line 13. As can be seen in FIG. 2, and is discussed in detail in the specification, this arrangement causes the first and second pore size ranges to be identifiably distinct. See FIG. 2 and Specification Page 6, lines 7-10 and Page 7 lines 4-5.

The second plurality of fibrils is substantially shorter than said first plurality of fibrils. See FIG. 2. Furthermore, this same kind of arrangement is repeated over again between a third node adjacent to said first node and a fourth node located adjacent said second node. Id.

Claim 32

Claim 32 is like claim 19 in that it includes limitations that the article is adapted for use as a tubular medical implant in blood-contact applications. See Specification Page 2, Lines 15-20. The scope of this claim is also different in that it claims that its longer fibrils "bypass" the intermediate node. For the purposes of this claim, the recitation of "third node" is meant to cover the same thing as the term "intermediate node" in claim 19. Thus, on FIG. 2 the third node recited in claim 32 is the middle node 8. FIG. 2 support for the claimed bypass arrangement can be seen in FIG. 2 where it is evident that the longer fibrils 4 go around the smaller third/intermediate node 8. Claim 32 also includes limitations that the article includes a "regularly repeated pore configuration throughout a substantial portion of said article" which is claimed in addition to the node/fibril arrangements disclosed in claim 19 and is evident from the illustrations and micrographs in the original disclosure. See, e.g., FIGs. 2-4.

Claim 37

Claim 37 covers some of the same subject matter included in claims 19 and 32, but is less specific in terms of the actual node/fibril arrangement. Further, claim 37 is more specific in terms of the size ranges of the two distinct pore groups. More specifically, claim 37 provides that the first group pores have "a first size range from about 2 to 15 microns in length" and that the second group pores have "a second size range from about 20 to 50 microns in length." These ranges are supported in the original Specification at Page 2, Line 35 – Page 3, Line 13.

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

A) Claims 19-27, 32-34, and 37-42 all stand rejected under 35 U.S.C. § 112; ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention.

B) Claims 19-22, 32-34, and 37-42 stand rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 6,039,755 issued to Edwin et al.

Appellants respectfully traverse these rejections.

VII. ARGUMENT

A) The § 112; ¶2 rejections should be reversed because the allegedly offending terms are reasonably definite

Section § 112; 2 requires that claims be drafted in a way that one skilled in the art is able to understand the metes and bounds of the claim. The examiner has rejected claims 19-22, 32-34, and 37-42 as being indefinite in violation of § 112; ¶2.

With respect to claim 19, the Examiner suggests that the limitation of "different molecular weight" is a relative term and thus indefinite. The use of the term "different," however, is universally identified as meaning not the same. Unless otherwise specified, these recitations would therefore mean that the molecular weights of the two materials used are not equal. It is agreed that this limitation is not terribly limiting considering that the use of a second material having a molecular weight only slightly different than that of the first would still read on the claim. But breadth is not the standard under § 112; ¶2, clarity is. See MPEP 2173.04. Thus, these rejections should be withdrawn.

The Examiner also suggests that the use of "intermediate node" in designating node 8 (See FIG. 2 reproduced above) in claims 19 and 37 and an interposed "third node" referred to in claim 32 leads to indefiniteness. It is somewhat difficult to match up all of the statements

made by the Examiner in support of his rejection with the actual claims rejected. These different wordings, however, are merely alternative expressions of the same thing and do not lead to indefiniteness

The idea that the "intermediate node" in claims 19 and 37 and that the interposed "third node" referred to in claim 32 are simply different ways to claim the same thing is immediately evident when the context for these terms is considered. For example, claim 19 describes the intermediate node as being "substantially smaller than said first and second nodes; a second plurality of fibrils attaching said intermediate node between said first and second nodes." Claim 32 similarly describes its "third node" as being "substantially smaller than said first and second nodes" and that is connected between the first and second nodes by "a second plurality of fibrils which are substantially shorter than said first plurality of fibrils." In short, it is perfectly clear that the two terms are being used interchangeably to describe the same thing when claim context is considered. Therefore, we believe that the indefiniteness rejections made by the Examiner should all be withdrawn.

B) The rejection of claims 19-22, 32-34, and 37-42 under 35 U.S.C. § 102(a) as being anticipated by Edwin was improper because the reference fails to show numerous claimed limitations

Claims 19 and 21

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). If a single element in any claim is not found in the reference relied on, a rejection under §102 is improper. "[T]he exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference." Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984).

The Evidence presented by the Examiner in support of his anticipation rejection of claim 19, as well as all the other art-based rejections, is U.S. Patent No. 6,039,755 issued to Edwin et al.

Like the ePTFE article of the claimed invention, the Edwin article is tubular (see Edwin FIGs. 1 and 2) and includes elongated nodes and fibrils. But the Edwin process of manufacture is much different. Compare Edwin Cols. 9 and 10 with Page 6, Lines 21-38 of Applicant's Specification. For example, Edwin uses a single ePTFE material whereas Applicant uses two different ePTFE materials having different molecular weights. The use of materials having different molecular weights is fundamental to the Applicant's process. Numerous other process differences exist.

Not surprising is that the microstructures in the articles resulting from the distinct processes are also much different. Review of the numerous Edwin micrographs reveals substantially uniform internodal distances between elongated nodes interconnected by fibrils. See, e.g., the illustration of FIG. 2 and all of the micrographs referenced by the examiner. All of these images show articles having substantially uniform internodal distances a' (see FIG. 2) between elongated nodes. This creates corresponding uniformity in the pore sizes in the Edwin article. See, e.g., FIGs. 5-24 in Edwin.

This substantial uniformity in Edwin's fibril/node/pore arrangements is not a triviality. It is, instead, a significant chief objective of the patent. This is evidenced by the two excerpts below.

> In contradistinction to the prior art, the present invention provides a radially, plastically deformable tubular ePTFE material, having a microstructure of nodes interconnected by fibrils, with the nodes being substantially perpendicular to the longitudinal axis of the tubular ePTFE material and the fibrils being oriented parallel to the longitudinal axis of the tubular ePTFE material. Radial expansion of the inventive ePTFE material deforms the ePTFE microstructure by

> elongating the nodes while substantially retaining the internodal distances (IND) between adjacent nodes in the longitudinal axis of the ePTFE tube.
>
> [Edwin Col. 2, Lines 41-52; emphasis added]
>
> Radial deformation of the ePTFE tubular member 10 is mediated by elongation of the plurality of nodes 14 to an elongated node length b' in the region of the ePTFE tubular member 10 where the positive pressure is exerted by the catheter balloon. As illustrated in FIG. 2 the entire ePTFE tubular member 10 is radially deformed to the larger diameter d'. One notable physical feature of the present invention is the elongation of the plurality of nodes 14 along their longitudinal axis while the post-expansion average internodal distances a' remains substantially the same as the internodal distance a of the non-radially deformed ePTFE tubular member 10.
>
> [Col. 10, Lines 19-30; emphasis added.]

It is also evidenced from the patented independent claims 1 and 14 in Edwin. Claim 1 was patented with the limitations of an article produced while "substantially retaining an average internodal difference throughout the radially deformed tubular structure." See Edwin Col. 22, Lines 7-9. Claim 14 contains equivalent language. See Edwin Col. 24.

Claim 19 in the current application includes limitations drawn to an article much different than that of Edwin. Claim 19 is reproduced below:

> 19. (previously amended) A PTFE article created by forming a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture, said article comprising:
>
> an internodal arrangement between a first node and a second node, said arrangement including a first plurality of fibrils interconnecting said first node with said second node, said first plurality of fibrils defining a first group of pores therebetween, said first group of pores falling substantially within a first size range;
>
> said arrangement also including an intermediate node which is substantially smaller than said first and second nodes; a second plurality of fibrils attaching said intermediate node between said first and second nodes,

said second plurality of fibrils defining therebetween a second group of smaller pores which fall substantially within a second size range;

said first and second size ranges being identifiably distinct;

said second plurality of fibrils being substantially shorter than said first plurality of fibrils; and

said arrangement being repeated between a third node adjacent to said first node and a fourth node located adjacent said second node.

[Emphasis added.]

The underlined limitations above are the ones not present in Edwin. First, the Edwin internodal arrangement is much different. The internodal arrangement exists between long first and second nodes. Connected between these first and second nodes by relatively short fibrils is an intermediate node. This is different than the Edwin arrangement which substantially includes elongated nodes interconnected by fibrils having substantially consistent internodal distances.

Another aspect is that Applicant's internodal distance is said to be repeated at least twice – once between the first node and an adjacent third node, and again between the second node and an adjacent fourth node. The repeated pattern in Edwin's illustrations and micrographs shows a repeated pattern of elongated nodes and elongated fibrils without any intermediate nodes.

Another claim 19 limitation missing in Edwin is that of two identifiably distinct groups of pores. Edwin is less than specific in describing pore sizes. But it is evident from the micrographs and other evidence that the reference can only be said to have one identifiably distinct group of pores because of its stated and shown embodiments having substantially averaged internodal distances. Certainly there is no mention of distinct groups of pores. Any deviations in Edwin's micrographs See Col. 2, lines 42-52 which stray from uniform

internodal distances are an aberration contrary to the goals of the patent. See Col. 10 lines 10-30.

The Examiner suggests that FIGs. 18D, 21B, and 21D show the node/fibril/pore arrangement of the present invention. These figures, however, simply do not show a repeated structure-within-a-structure arrangement like that claimed. Much less any consistent pattern of discretely-sized pores. At any time in Edwin that a node/fibril arrangement appears which is not in line with Edwin's uniform arrangement objectives, the pores are instead, radically orientated. Not part of any identifiably distinct arrangement like that claimed in claim 19.

Claim 19 contains limitations of: (i) a repeated internodal arrangement where an intermediate node is interconnected by short fibrils between two longer nodes; and (ii) identifiably distinct pore groups that are not found in Edwin. Therefore, the Edwin based rejections of claim 19 should be withdrawn.

Claims 21 and 22 depend from, and thus, include all the limitations of claim 19. Therefore, these claims would not be anticipated for the same reasons.

Claim 23

Dependent claim 23, after review in preparation for this appeal, appears to have antecedent basis problems under § 112; ¶2 because the "helical member" referred to does not appear in the claims from which it depends. Therefore, Applicant requests that this claim be rejected on those grounds. Applicant waives any notice requirement which might be required regarding this to this claim.

Claims 24-27

No art-based rejections were made of claims 24-27. Only rejections based on indefiniteness as discussed above. Therefore, it is believed that so long as the indefiniteness-based rejections are overcome, that these claims should be allowable despite Edwin.

Claim 32

Claim 32 is reproduced below:

> 32. (previously amended) An expanded PTFE article for use as a tubular medical implant comprising:
>
> a first material mixed with a second material to comprise a compound;
>
> said compound being expanded to create a regularly repeated pore configuration throughout a substantial portion of said article;
>
> said configuration comprising a first plurality of fibrils interconnecting a first node with a second node, said first plurality of fibrils defining a first plurality of pores therebetween;
>
> a third node which is substantially smaller than said first and second nodes;
>
> a second plurality of fibrils which are substantially shorter than said first plurality of fibrils, said second plurality attaching said third node between said first and second nodes, said second plurality of fibrils defining therebetween a second plurality of pores, said second plurality of pores being discrete from and smaller than said first plurality of pores; and
>
> said article being adapted for use in blood-contact applications.

Claim 32 is not anticipated for the same reasons as provided for claim 19 above. But this claim is even more limited than claim 19 in the sense that it requires that the two discrete groups of pores be regularly repeated throughout a substantial portion of the article. This claim also requires a bypass arrangement and other limitations not found in Edwin. Further, the

claim positively recites in its body that the article must be comprised of two different materials. Thus, in consideration of these reasons, we believe claim 32 should be allowed.

Claim 33

Claim 33 depends from claim 32 requires that the fibril/node/descrete pore arrangement be repeated throughout most of the article. This is not found in Edwin. Therefore, this claim should also be allowed.

Claim 34

Claim 34 depends from claim 19, and thus, is part of that independent claim group. In addition to the claim 19 requirements, this dependent claim requires that the claim 19 pore configuration be regularly repeated throughout a substantial portion of the article. Were the court to decide that the occasional random short node in Edwin were the equivalent of the intermediate nodes of claim 19, the claim 34 requirements that the patterns be regularly repeated throughout a substantial portion of the article would not be anticipated.

Claim 37

Claim 37 is slightly less specific than claims 19 and 32 in terms actual node/fibril arrangement, but it is more specific in terms of the size ranges of the two distinct pore groups. More specifically, claim 37 provides that the first group pores have "a first size range from about 2 to 15 microns in length" and that the second group pores have "a second size range from about 20 to 50 microns in length." The Examiner has made no record in the last office action which would provide support for the anticipation of these ranges. Therefore, we believe claim 37 should be allowed.

Claims 38 and 39

Claims 38 and 39 add limitations that the internodal arrangement is repeated in the article. These limitations were addressed in the commentary regarding claim 19 and that commentary is also relevant here. As stated regarding claim 19, Edwin does not disclose a repeated internodal fibril/node/pore arrangement where two discrete groups of pores exist. Therefore, claims 38 and 39 should also be allowed.

Claims 40 and 41

The Examiner suggests that claims 40 and 41 are anticipated for the same reasons provided for other claims. Careful review of the record, however, reveals that only earlier claims 24-27 have similar claim scope and that these claims were not rejected based on the Edwin reference, but only as being indefinite.

Regardless, careful review of Edwin reveals that it does not disclose two groups having the discrete ranges claimed. Therefore, these claims also contain allowable subject matter.

Claim 42

Claim 42 includes the limitation that the internodal arrangement is repeated substantially throughout the entire article. This is not shown in Edwin. Therefore, this claim also includes allowable subject matter.

Conclusion

Therfore, for all of the reasons noted above, Applicant respectfully requests that the pending claims be allowed and that this application pass on to issue.

Respectfully submitted,

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Claims Appendix

What the invention claimed is:

1-18. (cancelled)

19. (previously amended) A PTFE article created by forming a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture, said article comprising:

an internodal arrangement between a first node and a second node, said arrangement including a first plurality of fibrils interconnecting ~~a~~ said first node with ~~a~~ said second node, said first plurality of fibrils defining a first group of pores therebetween, said first group of pores falling substantially within a first size range;

said arrangement also including an intermediate node which is substantially smaller than said first and second nodes; a second plurality of fibrils attaching said intermediate node between said first and second nodes, said second plurality of fibrils defining therebetween a second group of smaller pores which fall substantially within a second size range;

said first and second size ranges being identifiably distinct;

said second plurality of fibrils being substantially shorter than said first plurality of fibrils; and

said arrangement being repeated between a third node adjacent to said first node and a fourth node located adjacent said second node.

20. (previously presented) The article of claim 19 wherein said first and second nodes are elongated and substantially parallel one to the other.

21. (previously presented) The article of claim 19 wherein the article is tubular.

22. (previously amended) The article of claim 19 wherein said third and fourth nodes are elongated and substantially parallel to said first and second nodes.

23. (previously presented) The article of claim 22 wherein said helical member is constructed of FEP.

24. (previously presented) The article of claim 19 wherein said first size range is from about 2 to 15 microns and said second range is from about 20 to 50 microns.

25. (previously presented) The article of claim 19 wherein said pores in said first size range are between 3 and 8 microns and said pores in said second range are between 25 and 40 microns.

26. (previously presented) The article of claim 19 wherein said pores in said first size range being between 4 and 8 microns and said pores in said second size range being between 25 and 40 microns.

27. (previously presented) The article of claim 19 wherein said pores in said first size range are about 5 microns and said pores in said second size range are about 30 microns.

28-31. (cancelled)

32. (previously amended) An expanded PTFE article for use as a tubular medical implant comprising:

a first material mixed with a second material to comprise a compound;

said compound being expanded to create a regularly repeated pore configuration throughout a substantial portion of said article;

said configuration comprising a first plurality of fibrils interconnecting a first node with a second node, said first plurality of fibrils defining a first plurality of pores therebetween;

a third node which is substantially smaller than said first and second nodes;

a second plurality of fibrils which are substantially shorter than said first plurality of fibrils, said second plurality attaching said third node between said first and second nodes, said second plurality of fibrils defining therebetween a second plurality of pores, said second plurality of pores being discrete from and smaller than said first plurality of pores; and

said article being adapted for use in blood-contact applications.

33. (previously presented) The article of claim 32 wherein said configuration is repeated throughout at least most of said article.

34. (previously presented) The article of claim 19 wherein said pore configuration is repeated regularly throughout a substantial portion of said article.

35. (cancelled).

36. (cancelled).

37. (previously presented) An expanded PTFE article for use as a medical implant comprising:

an internodal arrangement including an intermediate node which is interconnected between two a first transversely extending elongated node and a second transversely extending elongated node, a first group of pores being defined by a first group of fibrils which interconnect said intermediate node between said first and second elongated nodes;

said arrangement also including a second group of pores which are larger than and surround said first group of pores, said second group of pores being defined by fibrils which bypass said intermediate node and directly connect said first and second elongated nodes; and

said first group of pores having a first size range from about 2 to 15 microns in length and said second group of pores having a second size range from about 20 to 50 microns in length.

38. (previously presented) The article of claim 37 wherein said internodal arrangement is repeated between a third transversely extending elongated node which is adjacent said first transversely extending elongated node.

39. (previously presented) The article of claim 38 wherein said internodal arrangement is repeated between a fourth transversely extending elongated node which is adjacent said second elongated node.

40. (previously presented) The article of claim 37 wherein said first size range is between 3 and 8 microns in length and said second size range is between 25 and 40 microns in length .

41. (previously presented) The article of claim 37 wherein said first size range is between 4 and 6 microns in length and said second size range is between 25 and 35 microns in length.

42. (previously presented) The article of claim 37 wherein said internodal arrangement is repeated substantially throughout the entire article.

Evidence Appendix

None.

Related Proceedings Appendix

None.